K140419

TOGO MEDIKIT CO., LTD.
17148-6, Aza Kamekawa, Oaza Hichiya, Hyuga City
Miyazaki Prefecture 883-0062, Japan
TELEPHONE : +81-982-53-8027
FACSIMILE : +81-982-53-8008

MAY 1 2 2014

510(k) Summary

a. Owner/Company name, address

TOGO MEDIKIT CO., LTD.
17148-6 Aza Kamekawa, Oaza Hichiya
Hyuga City, Miyazaki, 883-0062, Japan

Daisuke Nagamizu
Manager, Regulatory Affairs Section, Quality Assurance Department
Phone: 011-81-982-53-8000
Fax: 011-81-982-53-8008
Email: qc@togomedikit.co.jp

b. Contact/Application Correspondent

Izumi Maruo
Senior Consultant
MIC International
4-1-17 Hongo, Bunkyo-ku
Tokyo, 113-0033, Japan

Phone: 011-81-3-3818-8577
Fax: 011-81-3-3818-8573
Email: maruo@mici.co.jp

c. Date prepared

January 20, 2014

d. Name of device

Trade Name:	SUPERCATH 5
Common Name:	Intravascular Catheter
Classification Name:	Catheter, Intravascular, Therapeutic, Short-term less than 30 days
Classification Regulation:	21 CFR 880.5200

TOGO MEDIKIT CO., LTD.
17148-6, Aza Kamekawa, Oaza Hichiya, Hyuga City
Miyazaki Prefecture 883-0062, Japan
TELEPHONE : +81-982-53-8027
FACSIMILE : +81-982-53-8008

e. Predicate devices

The SUPERCATH 5 is substantially equivalent to the following legally marketed devices:

510(k):	k093546
Trade name:	SUPERCATH 5
Product code:	FOZ

510(k):	k112290
Trade name:	SUPERCATH Z3V
Product code:	FOZ

Since the same name as predicate device is used, the new device under application is hereinafter called "the SUPERCATH 5 (PROPOSED)" and the predicate device is called "the SUPERCATH 5 (k093546)" for convenience of discussion in this application

f. Description of the device

The SUPERCATH 5 (PROPOSED) is intended to access a vein or artery and to administer fluids. The SUPERCATH 5 (PROPOSED) is designed for single use and for short-term use (less than 30 days), is designed to minimize inadvertent needlesticks and to reduce accidental needlesticks.

The SUPERCATH 5 (PROPOSED) catheter hub has a built-in check valve which together with the healthcare professional's finger pressure on the blood vessel, assists to reduce blood flashback when the metallic introducer needle is withdrawn following blood vessel puncture. The built-in check valve is not intended to stop bleeding completely. Pressing the button on the needle hub activates the coiled spring in the hub, retracting the metallic introducer needle into the needle hub.

The SUPERCATH 5 (PROPOSED) introducer needle has a side-notch to provide rapid visual confirmation of vessel entry. When the introducer needle is inserted into the vein, blood flows up and through the side-notch and returns down along the inside of the catheter tube.

The SUPERCATH 5 (PROPOSED) is available in 14G, 16G, 18G, 20G, 22G and 24G.

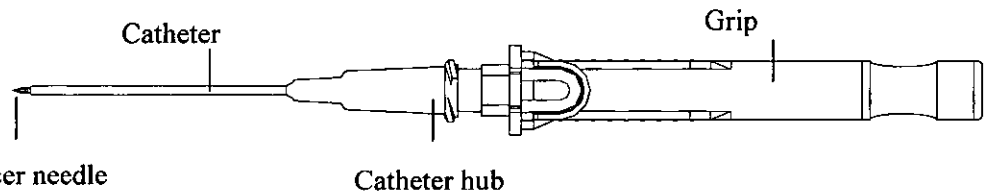

Figure 1. SUPERCATH 5

TOGO MEDIKIT CO., LTD.
17148-6, Aza Kamekawa, Oaza Hichiya, Hyuga City
Miyazaki Prefecture 883-0062, Japan
TELEPHONE : +81-982-53-8027
FACSIMILE : +81-982-53-8008

g. Indications for Use

Indication for Use
The SUPERCATH 5 is intended to access a vein or artery and to administer fluids. The SUPERCATH 5 is designed for single use and for short-term use (less than 30 days), is designed to minimize inadvertent needlesticks and to reduce accidental needlesticks.

h. Statement of substantial equivalence
The SUPERCATH 5 (PROPOSED) was essentially modified from the SUPERCATH 5 (k093546). Thus, most of the characteristics of the SUPERCATH 5 (PROPOSED) are similar to those of the SUPERCATH 5 (k093546). The similarities are:

- Same intended use
- Same catheter material (Polyurethane)
- Radiopaque
- Flashback Visualization
- Side-Notch Needle
- Needlestick Injury Prevention Feature
- Check Valve
- Ethylene Oxide Sterilized
- Single Sterile Wrapped
- Multiple Gauge Sizes and Needle Lengths

The SUPERCATH 5 (PROPOSED) contains the following modifications as compared to the SUPERCATH 5 (k093546):

- Addition of the adjustable attachment on the tip of the grip
- Addition of the wing and the tab on the catheter hub
- Modification of 18G and 20G introducer needle to include a side-notch (The side-notch is not included in 18G and 20G introducer needle of the predicate)
- Addition of models of 18G, 20G, and 22G without check valve
- Change of material formulation of plug and check valve
- Change of packaging sheet

The attachment is used just when manufacturing the SUPERCATH 5 (PROPOSED). The attachment is used in order to adjust the distance between the tip of the introducer needle and the tip of the catheter. After the adjustment, the attachment is fixed and users cannot move the attachment.
Regarding the tab, it avoids finger slipping when inserting the catheter. The wing is used in order to fix the catheter hub on the patient's body.

In order to evaluate any effects of the above changes on safety and effectiveness, biocompatibility testing, sterilization validation, and performance testing were performed. In conclusion, those analyses and testing demonstrated that the above listed modifications did not raise any new safety or effectiveness concerns.

i. Bench Testing

The following bench tests were performed to ensure the safety and effectiveness of the SUPERCATH 5 (PROPOSED), verify conformity to the recognized standards, and demonstrate substantial equivalence to the SUPERCATH 5 (k093546).

- Tensile Strength for the Catheter
  The tensile strength of the catheter meets acceptable minimum force until breakage when tested according to ISO 10555-1.
- Air and Liquid Leakage for the Hub Attachment
  The catheter hub is impervious to air/liquid infiltration when subjected to positive pressure and aspiration when tested according to ISO 10555-1.
- Flow rate
  The flow rate through catheter meets allowable limits when tested according to ISO 10555-5.
- Leakage at the Check Valve under pressure
  The built-in check valve is impervious to liquid infiltration when subjected to positive pressure according to in-house standard.
- Tensile Strength for the Wing
  The tensile strength of the wing meets acceptable minimum force until breakage when tested according to in-house standard.

j. Biocompatibility Testing

Color additives in the catheter hub of the SUPERCATH 5 (PROPOSED) are identical to those of another predicate, the SUPERCATH Z3V (k112290). Therefore, the biocompatibility test report for the SUPERCATH Z3V (k112290) is used for the color additives of the SUPERCATH 5 (PROPOSED). Regarding common components except color additives in the catheter hub, in order to evaluate biocompatibility for the finished SUPERCATH 5 (PROPOSED), we used the finished products of 14G of the SUPERCATH 5 (PROPOSED) as the samples for biocompatibility tests because 14G is the largest size. We performed following biocompatibility tests;

- Cytotoxicity
- Intracutaneous reactivity
- Delayed hypersensitivity
- Acute Systemic Toxicity
- Hemocompatibility
- Genotoxicity
- Pyrogen test
- LAL test
- Leachable test

In the biocompatibility testing reports, no biocompatibility concern was raised.

k. Simulated Clinical Use

The SUPERCATH 5 (PROPOSED) modified from the SUPERCATH 5 (k093546) has no new sharps injury prevention features which raise new safety and effectiveness concern. Therefore, the test report for the SUPERCATH 5 (k093546) is used in this application as for the SUPERCATH 5 (PROPOSED).

l. Conclusion

Based on the above discussion and enclosed sections regarding substantial equivalence to predicate devices, TOGO MEDIKIT concludes that the SUPERCATH 5 (PROPOSED) is substantially equivalent to the the SUPERCATH 5 (k093546) and the SUPERCATH Z3V (k112290) , and the SUPERCATH 5 (PROPOSED) does not raise any new questions regarding safety or effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

May 12, 2014

TOGO MEDIKIT Company, Limited
C/O Izumi Maruo
Senior Consultant
MIC International
4-1-17 Hongo, Bunkyo-ku
Tokyo, 113-0033
JAPAN

Re: K140419
Trade/Device Name: Supercath5
Regulation Number: 21 CFR 880.5200
Regulation Name: Intravascular Catheter
Regulatory Class: II
Product Code: FOZ.
Dated: January 20, 2014
Received: February 18, 2014

Dear Mr. Maruo:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mary S. Runner -S

Erin I. Keith, M.S.
Acting Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (If known): K140419

Device Name: SUPERCATH 5

Indication for Use

The SUPERCATH 5 is intended to access a vein or artery and to administer fluids. The SUPERCATH 5 is designed for single use and for short-term use (less than 30 days), is designed to minimize inadvertent needlesticks and to reduce accidental needlesticks.

Prescription Use X
(Per 21 CFR 801 Subpart D)

AND/OR

Over-the Counter Use _____
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

FDA

Digitally signed by
Richard C. Chapman
Date: 2014.05.12
09:00:15 -04'00'